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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/551,188	04/17/2000	Axel Ullrich	7683-165	1301

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EXAMINER

O HARA, EILEEN B

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 02/08/2002

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/551,188

Applicant(s)

ULLRICH ET AL.

Examiner

Eileen B. O'Hara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 November 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17,21,25 and 30 is/are pending in the application.
- 4a) Of the above claim(s) 17,21 and 25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 17,21,25 and 30 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9 and 16.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

1. Claims 17, 21, 25 and 30 are pending in the instant application.

Election/Restrictions

2. Applicant's election of Group IV (claim 30), in Paper No. 15 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 17, 21 and 25 are withdrawn as being drawn to a non-elected invention.

Claim 30 will be examined on the merits.

Priority

3. This application filed under former 37 CFR 1.60 lacks the current status of the nonprovisional parent application 08/153,397. A statement reading "(now United States Patent No. 6,051,397)" should be included after "08/153,397 filed November 16, 1993" following the title of the invention or as the first sentence of the specification.

Specification

4. The disclosure is objected to because of the following informalities:
 - 4.1 37 C.F.R. §1.821(d) states:

Where the description or claims of a patent application discuss a sequence that is set forth in the "Sequence Listing" in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO:" in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application.

Sequences are disclosed in Figures 1, 3 and 4 without the required reference to the sequence identifiers (SEQ ID NOS:). Also, the instant specification needs to be amended so that it complies with 37 C.F.R. § 1.821(d) which requires a reference to a particular sequence identifier (SEQ ID NO:) be made in the specification and claims wherever a reference is made to that sequence. This can be resolved by adding a reference to the Figures or the Brief Description of the Drawings. For rules interpretation Applicant may call (703) 308-1123. See M.P.E.P. 2422.04.

Applicants are required to amend the specification and claims to comply with 37 C.F.R. §1.821(d).

4.2 On page 8, line 30, "SEQ ID NO. 2" be inserted after "SEQ ID NO. 1" to clarify that SEQ ID NO. 2 is the amino acid sequence.

4.3 On page 11, the sentence spanning lines 2-6 does not make sense as written because of the word "with" on line 3.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 30 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

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The instant specification discloses a nucleic acid identified as MCK-10 and various splice variants (MCK-10-1, MCK-10-2, MCK-10-3, MCK-10-4, Figure 2) encoding a protein that is identified as a receptor tyrosine kinase, originally isolated from a mammary carcinoma cDNA library, that is part of the transmembrane insulin receptor family. MCK-10 has an extracellular ligand-binding domain and an intracellular tyrosine kinase domain, and it believed to be involved in normal cellular responses. The specification discloses that MCK-10 nucleic acids are expressed in a number of normal tissue, epithelial cells, a wide variety of cancer cell lines and was expressed in all tumors tested. The nucleic acids and proteins therefore have diagnostic utilities, and the protein can be used to identify agonists or antagonists or binding compounds and is enable for this use. However, claim 30 is drawn to a method of modulating the endogenous enzymatic activity of the tyrosine kinase MCK-10 in a mammal by administering a ligand to the MCK-10 receptor, and there is no known ligand which binds to and modulates the enzymatic activity of the receptor, so therefore the disclosure is not enabled for this method. Additionally, there is no assay taught which would enable the skilled artisan to determine if a potential ligand administered to a mammal actually modulated the activity of the receptor. The specification does not provide adequate guidance as to how to perform the method of claim 30, and therefore the claim is not enabled for the method.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is undue include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of

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direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (FED. Cir. 1988).

It is acknowledged that the level of skill of those in the art is high. It is not disclosed and not predictable from the limited teachings of the prior art and specification what ligand would modulate the activity of the MCK-10 receptor. The specification does not provide any working examples in which a ligand administered to a mammal will modulate the endogenous activity of the MCK-10 protein, and no guidance as to what such a ligand would be. The specification has not provided the person of ordinary skill in the art the guidance necessary to be able to modulate the activity of the MCK-10 receptor in a mammal.

Due to the large quantity of experimentation necessary to develop an assay to determine what compounds would modulate the activity of the MCK-10 receptor in a mammal, the lack of direction/guidance presented in the specification regarding same, the absence of working examples, the teachings of the prior art that do not identify or even suggest a possible ligand, and the complex nature of the invention, undue experimentation would be required of the skilled artisan to use the claimed invention. Additionally, the specification has not provided guidance as to why the skilled artisan would want to modulate the activity of the MCK-10 receptor, since the downstream effects of the receptor's activity are not known. What Applicant has provided is a mere wish or plan and an invitation to experiment.

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6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 30 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 30 encompasses a method of modulating the endogenous enzymatic activity of the tyrosine kinase MCK-10 in a mammal by administering a ligand to the MCK-10 receptor. The protein identified as MCK-10 in the instant application has the amino acid sequence shown in SEQ ID NO: 2, but since the claim recites "the MCK-10 receptor" and does not require any structure, it is considered indefinite, because the resulting claim does not clearly set forth the metes and bounds of the patent protection desired.

Conclusion

7. Claim 30 is rejected.

The art considered pertinent to the present application is Barker et al., WO 95/02187 (cited by Applicant), which discloses a nucleic acid identified as a PTK, a receptor tyrosine kinase that is 91.3% identical to nucleotides 181-3950 of SEQ ID NO: 1 of the present application. This reference does not teach or suggest what is being claimed, but is cited as the DNA having the closest homology.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (703) 308-3312. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers Before Final filed by RightFax should be directed to (703) 872-9306.

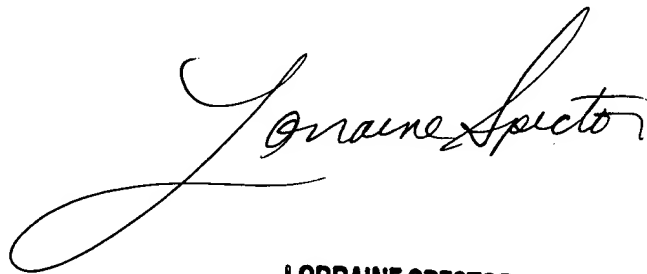
Official papers After Final filed by RightFax should be directed to (703) 872-9307.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Eileen B. O'Hara, Ph.D.

Patent Examiner

A handwritten signature in cursive script that reads "Lorraine Spector". The signature is written in black ink and is positioned above the printed name and title.

**LORRAINE SPECTOR
PRIMARY EXAMINER**